UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORION CORPORATION, Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES, LIMITED, Defendant.	Case No. 07-CV-05436 (MLC/JHH)
ORION CORPORATION, Plaintiff, v. SUN PHARMA GLOBAL, INC., Defendant.	Case No. 08-CV-5545 (MLC/JHH) **CONSOLIDATED**

DEFENDANT SUN PHARMA GLOBAL, INC'S FIRST AMENDED ANSWER AND COUNTERCLAIMS

Defendant Sun Pharma Global, Inc., ("Defendant" or "Sun Global"), hereby responds in this First Amended Answer and Counterclaims to the allegations in the Complaint filed on November 12, 2008, in case No. 3:08-cv-05545 [D.I. 1], by Plaintiff Orion Corporation, (hereinafter "Orion" or "Plaintiff"), as set forth below in response to the numbered paragraphs of the Complaint:

ANSWER

JURISDICTION AND PARTIES

1. Sun Global is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies the same.

2. Sun Global admits that it is incorporated in the British Virgin Islands and maintains a post office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. Sun Global admits that it is an alien corporation.

3. Sun Global admits that it is a wholly-owned subsidiary of Sun Pharmaceutical Industries Limited, (hereinafter "Sun Ltd."). Sun Global admits that Sun Ltd. is an Indian Company and maintains an office at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400059, Maharashtra, India Ltd.

4. Sun Global admits that Sun Ltd. is a Defendant in Civil Action No. 3:07-cv-05436-MLC-JJH (consolidated) in this Court with Plaintiff Orion regarding a product that contains entacapone.

5. Sun Global denies that Caraco Pharmaceutical Laboratories, Ltd., (hereinafter "Caraco"), is a majority-owned subsidiary of Sun Global. Sun Global is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

6. Sun Global denies that it has numerous contracts with Caraco for the exclusive manufacturing, distribution, and marketing of generic drugs in the United States.

7. Sun Global admits that the Court has personal jurisdiction over Sun Global solely because Sun Global has agreed to consent to personal jurisdiction of this Court for the purposes

of this litigation. Sun Global denies that the Court has personal jurisdiction over it for any other reason.

8. Sun Global admits that this purports to be an action for patent infringement arising under the patent laws of the United States and that this Court has subject matter jurisdiction over the asserted claims. Sun Global admits that venue is proper in this judicial district under 28 U.S.C. §1391(c) because it has consented to personal jurisdiction for the purposes of this litigation only, and under 28 U.S.C. § 1391(d) because Sun Global is an alien corporation.

FACTUAL BACKGROUND

9. Sun Global admits that the face of the patent shows that United States Patent No. 5,446,194 ("the '194 patent") issued on August 29, 1995. Sun Global denies that the '194 patent was duly and legally issued. Sun Global is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

10. Sun Global admits that Orion is the holder of a New Drug Application, ("NDA"), approved by the United States Food and Drug Administration, ("FDA"), for the use of entacapone, but because FDA approval for the product is narrower than characterized, denies the remaining allegations of this paragraph.

11. Sun Global is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

12. Sun Global admits that it has submitted to the FDA an Abbreviated New Drug Application, ("ANDA"), under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, importation, and sale of entacapone tablets, 200 mg, but denies that the ANDA seeks broad approval for treatment of Parkinson's disease. Sun Global is without knowledge or

information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

13. Sun Global admits that it filed its ANDA, assigned ANDA number 90-690, to obtain approval to market a generic version of entacapone. Sun Global denies the remaining allegations of this paragraph because the '194 patent is invalid.

14. Sun Global admits the allegations of this paragraph.

15. Sun Global admits that its counsel sent a letter dated October 3, 2008 (hereinafter, "Notice"), to Orion to notify Orion that Sun Global had submitted an ANDA for generic entacapone tablets, that the letter provided information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), and that Orion received the letter on October 6, 2008. Sun Global is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

16. Sun Global admits that Sun Global's tablets will have the same indications as that of the FDA-approved Comtan® and will have the same dosage instructions as those contained in the FDA-approved Comtan® tablet product package insert.

17. On information and belief, Sun Global admits the allegations of this paragraph.

18. On information and belief, Sun Global denies that entacapone/carbidopa/levodopa is broadly approved for treatment of Parkinson's disease. On information and belief, Sun Global admits the other allegations of this paragraph

19. On information and belief, Sun Global admits the allegation of this paragraph.

20. Sun Global denies that it has numerous contracts with Caraco for the exclusive manufacturing, distribution, and marketing of generic drugs in the United States, and so denies the allegations of this paragraph.

21. On information and belief, Sun Global admits the allegation of paragraph 21 of the Complaint

COUNT I
PATENT INFRINGEMENT OF THE '194 PATENT

22. Sun Global incorporates by reference, as though fully set forth, paragraphs 1-21 herein.

23. Sun Global denies the allegations of this paragraph.

24. Sun Global denies the allegations of this paragraph.

COUNT II
DECLARATORY JUDGMENT IN FAVOR OF THE '194 PATENT

25. Sun Global incorporates by reference, as though fully set forth, paragraphs 1-24 herein.

26. Sun Global has not reached a final decision regarding the allegations of this paragraph, and therefore denies them.

27. Sun Global has not reached a final decision regarding the allegations of this paragraph, and therefore denies them.

28. Sun Global denies the allegations of this paragraph.

29. Sun Global denies the allegations of this paragraph.

COUNT III
EXCEPTIONAL CASE

30. Sun Global incorporates by reference, as though fully set forth, paragraphs 1-29 herein.

31. Sun Global denies the allegations of this paragraph.

32. Sun Global denies the allegations of this paragraph.

PRAYER FOR RELIEF

The allegations contained in the Prayer for Relief do not require a response, but to the extent that the Prayer for Relief contains additional allegations, Sun Global denies them all and denies that Orion is entitled to any relief from Sun Global. Wherefore, Sun Global demands Judgment dismissing plaintiff's Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

33. Orion's Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Failure to Join a Necessary and/or Indispensable Party)

34. Orion's claims are barred because it has failed to join one or more necessary and/or indispensible parties.

THIRD AFFIRMATIVE DEFENSE
(Invalidity of the '194 Patent)

35. The claims of the '194 patent are invalid under 35 U.S.C. § 101 et seq., including 35 U.S.C. §§ 101, 102, 103, 112, 121, 156 and/or 253.

FOURTH AFFIRMATIVE DEFENSE
(Noninfringement of the '194 Patent)

36. Sun Global is not infringing, has not infringed, and will not infringe, directly or indirectly, any valid and enforceable claim of the '194 patent, either literally or under the doctrine of equivalents.

FIFTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel)

37. Any assertion by Orion that the claims of the '194 patent cover and include the products or acts of Sun Global are barred by the doctrine of prosecution history estoppel or otherwise by virtue of admissions, amendments, arguments, representations and/or misrepresentations made to the United States Patent and Trademark Office during the prosecution of the application from which the '194 patent issued.

SIXTH AFFIRMATIVE DEFENSE
(Unclean Hands)

38. Orion is barred from any recovery because of unclean hands.

COUNTERCLAIMS

Counterclaimant Sun Global by way of Counterclaim for Declaratory Judgment against Orion alleges as follows:

I. THE PARTIES

1. Counterclaimant Sun Global is incorporated in the British Virgin Islands and is a wholly owned subsidiary of Sun Pharmaceutical Industries Limited, a public limited liability company incorporated and existing under the laws of India with its principal place of business in Mumbai, India.

2. Upon information and belief, Counterclaim Defendant Orion is a corporation organized and existing under the laws of Finland with its principal place of business in Espoo, Finland.

II. THE PATENTS-IN-SUIT

3. The patents-in-suit are United States Patent No. 5,446,194 ("the '194 patent"), issued on August 29, 1995, and United States Patent No. 6,599,530, ("the '530 patent"), issued

on July 29, 2003. Sun Global submitted ANDA No. 90-690, pursuant to 21 U.S.C. § 355(j), containing Paragraph IV certifications with respect to the '194 patent and the '530 patent. A copy of the '530 patent as obtained from the U.S. Patent and Trademark Office is attached hereto as Exhibit 1.

III. JURISDICTION AND VENUE

4. Counterclaimant Sun Global brings this action for a declaratory judgment of patent non-infringement against Orion. This action arises under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and the Patent Laws of the United States of America, 35 U.S.C. §§ 101, *et seq.*

5. Orion submitted to the U.S. Food and Drug Administration ("FDA") the '194 patent and the '530 patent for listing in "Approved Drug Products with Therapeutic Equivalence Evaluations," (the "Orange Book"), for Comtan®.

6. On October 6, 2008, Orion received from Sun Global a notice letter pursuant to 21 U.S.C. § 355 (j)(2)(B), (the "Notice"), indicating that Sun Global's ANDA No. 90-690 was filed, and that the ANDA included Paragraph IV certifications for both the '194 patent and the '530 patent. The Notice related, *inter alia,* to invalidity, non-infringement, and/or unenforceability, and included an Offer of Confidential Access to the ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). The Notice included a Detailed Statement entitled "Non-Infringement of all Claims of the '530 Patent." A copy of the Notice, which includes the Detailed Statement relating to the '530 patent, is attached hereto as Exhibit 2.

7. On or about November 12, 2008, Orion filed a complaint against Sun Global for infringement of the '194 patent. However, Orion did not file a complaint against Sun Global for infringement of the '530 patent within 45 days of October 7, 2008, i.e., by November 20, 2008.

8. Under 21 U.S.C. § 355(j)(5)(C)(i)(I) and 35 U.S.C. § 271 (e)(5), a justiciable declaratory judgment controversy exists when an ANDA applicant is not sued within 45 days of the listed patent owner's receipt of a Notice of Paragraph IV certification relating to non-infringement, which is also accompanied by an Offer of Confidential Access.

9. A justiciable controversy exists for the '194 patent because Orion has asserted patent infringement of the '194 patent in this District Court.

10. A justiciable controversy exists for the '530 patent because Orion has not brought suit against Sun Global for patent infringement of the '530 patent pursuant to 35 U.S.C. § 271(e)(2)(a) within 45 days of receiving the Notice and Offer of Confidential Access, i.e., 45 days from October 6, 2008.

11. Subject matter jurisdiction over the counterclaims is proper pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. Orion is subject to general personal jurisdiction in this judicial district. Moreover, Orion has purposefully availed itself of the privileges of this District through the filing of a complaint in this District alleging infringement of the '194 patent. Venue is proper in this District under 28 U.S.C. §§ 1391(c) or (d).

IV. FACTUAL BACKGROUND

A. Terminal Disclaimer

13. The '194 patent issued from a chain of applications starting with U.S. Patent Application No. 07/126,911 filed on November 27, 1987. Based on information and belief, the '194 patent has an original expiration date of August 29, 2012.

14. U.S. Patent No. 4,963,590 (the '590 patent) issued on October 16, 1990 from U.S. Application No. 07/126,911, filed November 27, 1987. Based on information and belief, the '590 patent has an original expiration date of November 27, 2007.

15. There is no Terminal Disclaimer under 35 U.S.C. § 253 or 37 C.F.R. § 1.321 in the '194 patent terminally disclaiming any portion of its patent term that would extend past the expiration date of the '590 patent.

16. U.S. Patent No. 5,135,950 (the '950 patent) issued on August 4, 1992 from U.S. Patent Application No. 07/606,717 filed on October 31, 1990. Based on information and belief, the '950 patent has an original and current expiration date of October 31, 2010.

17. There is no Terminal Disclaimer under 35 U.S.C. § 253 or 37 C.F.R. § 1.321 in the '194 patent terminally disclaiming any portion of its patent term that would extend past the expiration date of the '950 patent.

B. Hatch-Waxman Extension

18. Under certain circumstances, 35 U.S.C. § 156 provides for an extension of patent term due to delays in obtaining FDA regulatory approval to market a drug (a "Hatch-Waxman extension").

19. A Hatch-Waxman extension may only be given for the first U.S. regulatory approval of a drug, including any salt or ester of the drug. 35 U.S.C. § 156 (a)(5).

20. Based on information and belief, Orion requested, and was granted, a Hatch-Waxman patent term extension of the '194 patent based on the regulatory review period of Comtan®.

21. Based on information and belief, the Hatch-Waxman extension extended the term of the '194 patent listed for Comtan® from its original expiration date to October 19, 2013.

22. Based on information and belief, the Hatch-Waxman extension was based on the original expiration date of the '194 patent. In seeking the Hatch-Waxman extension, Orion did not indicate to the U.S. Patent and Trademark Office (US PTO) or to FDA that the '194 patent should be terminally disclaimed over the '590 and/or '950 patents.

23. Based on information and belief, the Hatch-Waxman extension was calculated based on incorrect information provided by Orion to the US PTO and to FDA.

24. A Hatch-Waxman extension does not extend to all products protected by the patent, but only to the product on which the extension was based. 35 U.S.C. § 156 (b)(1).

25. Orion has FDA approval to market two products containing the active ingredient entacapone. FDA approved Orion's first entacapone product, Comtan®, on October 19, 1999, based on NDA 20-796. FDA's approval of Comtan® constituted the first regulatory approval of entacapone, or of any salt or ester thereof.

26. FDA first approved Orion's second entacapone product, Stalevo®, on June 11, 2003, based on NDA 21-485. FDA's approval of Stalevo® was not the first regulatory approval of entacapone, or of any salt or ester thereof, because FDA had previously approved Comtan®.

27. Based on information and belief, the Hatch-Waxman patent term extension of the '194 patent was not based on the regulatory review period of Stalevo®.

28. Based on information and belief, after the Hatch-Waxman extension was granted (based on the regulatory review period of Comtan®), Orion submitted, or caused to be submitted, a request indicating to FDA that the '194 patent listed in the Orange Book for Stalevo® expires on October 29, 2013.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '194 PATENT

29. Counterclaimant Sun Global has not, does not, and will not directly infringe, contributorily infringe or induce others to infringe any valid claim of the '194 patent, either literally or under the doctrine of equivalents. Accordingly, Sun Global is entitled to declaratory judgment of noninfringement of the '194 patent.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '530 PATENT

30. Counterclaimant Sun Global has not, does not, and will not directly infringe, contributorily infringe or induce others to infringe any valid claim of the '530 patent, either literally or under the doctrine of equivalents. Accordingly, Sun Global is entitled to declaratory judgment of noninfringement of the '530 patent.

No Literal Infringement

31. Claim 1 of the '530 patent recites:

> An oral compacted composition in the form of a tablet, which comprises a pharmaceutically effective amount of entacapone, nitecapone, or pharmaceutically acceptable salt of entacapone or nitecapone, and croscarmellose sodium in an amount of at least 6% by weight of the composition.

32. Claim 11 of the '530 patent recites:

> An oral compacted composition in the form of a tablet, which comprises from about 100 mg or 200 mg of entacapone or pharmaceutically acceptable salt thereof, and croscarmellose sodium in an amount of at least 6% by weight of the composition.

33. Claim 12 of the '530 patent recites:

> A method for preparing an oral compacted composition in the form of a tablet wherein the composition comprises entacapone, nitecapone, or a pharmaceutically acceptable salt of entacapone or nitecapone, and the croscarmellose sodium in an amount of at least 6% by weight of the composition, which comprises: a) mixing a pharmaceutically effective amount of entacapone, nitecapone, or pharmaceutically acceptable salt of entacapone or nitecapone, one or more auxiliary agents and croscarmellose sodium to obtain a first mixture; b) compacting and crushing the first mixture one or more times to obtain a

plurality of granules; c) adding a lubricant, a glidant, or a mixture thereof to the granules to obtain a second mixture; and d) compressing the second mixture into a tablet.

34. The Notice states:

The tablets comprise 4.85% by weight croscarmellose based on weight of the coated tablet, and 5% by weight croscarmellose based on weight of the uncoated tablet.

35. The Notice states:

Sun's proposed tablet composition does not include croscarmellose sodium in an amount of at least 6% by weight of the composition. Rather, the Sun's proposed entacapone tablet contains 4.85% by weight of the croscarmellose sodium of the coated tablet and 5% by weight of the uncoated tablet.

36. According to the Notice, Sun's finished entacapone tablets comprise 4.85% by weight croscarmellose sodium.

37. Pursuant to a discovery request by Orion in case 07-CV-05436 in the District Court for the District of New Jersey Sun produced to Orion's counsel a copy of ANDA No. 90-690.

38. A redacted copy of a page from ANDA 90-690 with Bates Number SUN045548 is attached as Exhibit 3. Orion's counsel in this case has an un-redacted copy of this page, which is designated "HIGHLY CONFIDENTIAL."

39. According to ANDA 90-690, Sun's finished entacapone tablets comprise 4.85% by weight croscarmellose sodium.

40. 4.85% by weight croscarmellose sodium is less than 6% by weight croscarmellose sodium.

41. 5% by weight croscarmellose sodium is less than 6% by weight croscarmellose sodium.

42. Because 4.85% croscarmellose by weight and 5% croscarmellose by weight are less than 6% croscarmellose by weight, the product of ANDA No. 90-690 does not literally infringe independent claims 1, 11, and 12 of the '530 patent.

43. Claims 2-10 of the '530 patent depend directly or ultimately from claim 1.

44. Claims 13-20 of the '530 patent depend directly or ultimately from claim 12.

45. The manufacture, use, sale, offer for sale, or importation into the United States of Sun Global's entacapone product does not, and will not, literally infringe any claim of the '530 patent.

No Infringement Under the Doctrine of Equivalents

46. The application that issued as the '530 patent (U.S. Serial No. 09/152,263, "the '263 application") was filed on September 14, 1998. A copy of the '263 application is attached hereto as Exhibit 4.

47. In Column 1, the '530 patent states:

> Croscarmellose sodium is a cross-linked polymer of carboxymethyl-cellulose sodium. According to the Handbook of Pharmaceutical Excipients (Ainley Wade and Paul J. Weller, Second Edition, The Pharmaceutical Press, London, 1994), it is used in oral pharmaceutical formulations as a disintegrant for tablets, capsules, and granules. Typically, concentrations from 0.5 to 5% w/w are used as a tablet disintegrant.

48. In column 2, the '530 patent states:

> A further object of the invention is to provide a tablet comprising entacapone, nitecapone, or a pharmaceutically acceptable salt thereof and croscarmellose sodium, wherein the amount of croscarmellose sodium is at least 6% by weight, more preferably from about 8% to about 16% by weight, especially from about 10% to about 14% by weight.

49. In column 3, the '530 patent states:

> Applicants have surprisingly discovered that the best dissolution results for the oral compacted compositions of the invention are achieved when the amount of croscarmellose sodium is far more than what is suggested in the art. Accordingly, it has been found that the amount of croscarmellose sodium in the oral compacted composition is preferably at least 6% by weight. More preferably, the amount of croscarmellose

sodium is from about 8% to about 16% by weight, especially from about 10% to 14% by weight.

50. As filed, the '263 application had 20 claims, of which claims 1, 11 and 19 were independent.

51. Independent claim 1 as originally filed recited:

An oral compacted composition comprising a pharmaceutically effective amount of entacapone, nitecapone or a pharmaceutically effective salt thereof and croscarmellose sodium.

52. Independent claim 11 as originally filed recited:

A method for making an oral compacted composition comprising entacapone, nitecapone or a pharmaceutically acceptable salt thereof, wherein the method comprises:

a) mixing a pharmaceutically effective amount of entacapone, nitecapone , or a pharmaceutically acceptable salt thereof, one or more auxiliary agents and croscarmellose sodium to obtain a first mixture;

b) compacting and crushing the first mixture one or more times to obtain a plurality of granules;

c) adding a lubricant, a glidant, or a mixture thereof to the granules to obtain a second mixture; and

d) compressing the second mixture into a plurality of tablets.

53. Independent claim 19 as originally filed recited:

A method of inhibiting catechol-O-methyltransferase, wherein the method comprises administering to a patient in need thereof an oral compacted composition, comprising entacapone, nitecapone, or a pharmaceutically acceptable salt thereof.

54. None of the independent claims as filed included a limitation requiring that a minimum percentage of croscarmellose sodium be present in the recited compositions.

55. A non-final Office Action dated November 5, 1999 (copy attached hereto as Exhibit 5) stated:

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,446,194 ('194) in view of US patent No 5,489,614 (hereafter '614") US patent 5,380,535 ('535) . . . .

56. The November 5, 1999, Office Action stated:

However, it is the position of the examiner that, in view of the teachings of dispersion agents desired by '614 in a formulation of catechol derivatives, it would have been obvious for a skilled artisan at the time of the invention to add croscarmellose sodium ('535) to the formulation containing catechol derivatives such as entacapone or nitecapone ('194). Croscarmellose sodium is a well known dispersing or disintegrating agent in the art and can be added to any pharmacological formulation with an expectation to control the release rate of the active agents in the formulation. Further, preparing a compressed oral formulation and optimizing the amounts of additives, including the sequence of adding the additives without affecting the pharmacological activity of the active ingredient, is within the scope of a skilled artisan.

57. Applicants' Amendment dated May 4, 2000 (copy attached hereto as Exhibit 6), stated:

In order to establish a *prima facie* case of obviousness based on a combination of references, there must be, *inter alia*, some motivation in the art to combine the references a suggested by the Examiner. MPEP §2143. There is no such motivation in this instance.

58. Applicants' Amendment dated May 4, 2000, stated:

Even if the Examiner could establish a *prima facie* case of obviousness, the Examiner's showing would be rebutted by the evidence of record that demonstrates the unexpected advantages of the claimed compositions.

59. Applicants' Amendment dated May 4, 2000 stated:

As noted in the present specification, croscarmellose sodium is unexpectedly better for releasing entacapone, nitecapone, or pharmaceutically acceptable salts thereof from an oral compacted composition than other common dissolution improving agents.

60. A final Office Action dated May 24, 2001 (copy as obtained from the U.S. PTO attached as Exhibit 7), stated:

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,446,194 ('194- Backstrom et al) in view of US patent No 5,489,614 (hereafter '614 - Korkolainen) and US patent 5,380,535 ('535 - Geyer).

61. The May 24, 2001, Office Action stated:

However, it is the position of the examiner that, in view of the teachings of dispersion agents desired by '614 in a formulation of catechol derivatives, it would have been obvious for a skilled artisan at the time of the invention to add croscarmellose sodium ('535) to the formulation containing catechol derivatives such as entacapone or

> nitecapone ('194). Croscarmellose sodium is a well known dispersing or disintegrating agent in the art and can be added to any pharmacological formulation with an expectation to control the release rate of the active agent in the formulation. Further, preparing a compressed oral formulation and optimizing the amounts of additives, including the sequence of adding the additives without affecting the pharmacological activity of the active ingredient is within the scope of a skilled artisan.

62. Applicants' Request for Reconsideration dated October 29, 2001 (attached hereto as Exhibit 8), stated:

> Those skilled in the art do not necessarily consider a certain amount of one disintegrant as equivalent to the same amount of another. The Figures in the present application show a comparison of compositions containing very high, and most often unconventionally high, amounts of disintegrants. When compared under at least those conditions, croscarmellose sodium performs unexpectedly better than the comparative disintegrants.

63. Applicants' Request for Reconsideration dated October 29, 2001, stated:

> The composition tested in the Examples of this application share the common thread of using very high amounts of disintegrants, and thus the comparison between them is relevant to the issue of unexpected advantages of the invention.

64. An Advisory Action dated November 19, 2001 (attached hereto as Exhibit 9, emphasis in original), stated that the request for reconsideration:

> does NOT place the application in condition for allowance because: instant claims, except claims 4-6 and 12-14, do not recite any amounts of croscaramellose [*sic*]. Further, Applicnats [*sic*] state that unconvetionally [*sic*] high amounts of croscaramellose [*sic*] used by applicants is not obvious. However, it is not clear which of the specific amounts of croscaramellose [*sic*] claimed in the instant is unconventionally high. Furthermore, applicants state that those skilled in the art do not necessarily consider a certain amount of one disintegrant as equivalent to the same amount of another. However, applicants have not shown any evidence or proof to that effect, therefore, the rejection is deemed proper.

65. A Continued Prosecution Application was filed on or about February 12, 2002, with a Preliminary Amendment canceling claim 1-20 and adding claims 21-42, of which claims 21, 32, and 33 were independent. A copy of the Preliminary Amendment is attached hereto as Exhibit 10.

66. As added in the Preliminary Amendment, new claim 21 recited:

21. (New) An oral compacted composition in the form of a tablet, which comprises a pharmaceutically effective amount of entacapone, nitecapone, or pharmaceutically acceptable salt of entacapone or nitecapone, and croscarmellose sodium.

67. As added in the Preliminary Amendment, new claim 32 recited:

32. (New) An oral compacted composition in the form of a tablet, which comprises from about 100 mg to 200 mg of entacapone or pharmaceutically acceptable salt thereof, and croscarmellose sodium in an amount of at least 6% by weight of the composition.

68. As added in the Preliminary Amendment, new claim 33 recited:

33. (new) A method for preparing an oral compacted composition in the form of a tablet, wherein the composition comprises entacapone, nitecapone, or a pharmaceutically acceptable salt of entacapone or nitecapone, which comprises:

a) mixing a pharmaceutically effective amount of entacapone, nitecapone , or pharmaceutically acceptable salt of entacapone or nitecapone, one or more auxiliary agents and croscarmellose sodium to obtain a first mixture;

b) compacting and crushing the first mixture one or more times to obtain a plurality of granules;

c) adding a lubricant, a glidant, or a mixture thereof to the granules to obtain a second mixture; and

d) compressing the second mixture into a tablet.

69. The Preliminary Amendment, in the Remarks section, stated:

Taken from the point of view of one skilled in the art not having knowledge of the present application, the breadth of the Korkolainen disclosure cited by the Examiner does not appear to contain the specificity needed to have turned that person skilled in the art in the direction of choosing particular dispersion forming ingredients over others, let alone choosing croscarmellose sodium.

70. A non-final Office Action dated April 24, 2002 (attached hereto as Exhibit 11), stated:

Claims 21-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,489,614 to Backstrom et al (hereafter Backstrom) and Remington: the science and practice of Pharmacy (hereafter Remington).

71. The Office Action dated April 24, 2002, stated:

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add 2% to 4% croscarmellose of Remington to the tablet composition of Backstrom containing entacapone and nitecapone because Remington suggests that croscarmellose is a super disintegrant that swells rapidly causing the

disintegration of the tablet and allow for the rapid dissolution of the active agent from the tablet.

72. Following a Response dated July 5, 2002, an Office Action dated September 20, 2002, finally rejected claims 21-41.

73. An Interview Summary form (attached hereto as Exhibit 12) indicates that an interview between the Examiner and Steven Scott took place on February 26, 2003.

74. The Interview Summary states:

> Counsel explained the unexpected requirement of high amounts of croscarmellose, than those conventionally taught by prior art (Remington's) for a complete dissolution of the claimed compounds. Examiner will consider the arguments presented by counsel in determining the patentability of claim 24.

75. At the time of the Interview Summary, dependent claim 24 recited:

> An oral compacted composition according to claim 21, which comprises croscarmellose sodium in an amount of at least 6% by weight of the composition.

76. Applicants' Amendment dated February 28, 2003 (attached hereto as Exhibit 13), amended independent claim 21. The Appendix Detailing Amendments to the Claims presents amended claim 21 as (underlining in original):

> 21. (Amended) An oral compacted composition in the form of a tablet, which comprises a pharmaceutically effective amount of entacapone, nitecapone, or pharmaceutically acceptable salt of entacapone or nitecapone, and croscarmellose sodium <u>in an amount of at least 6% by weight of the composition</u>.

77. Applicants' Amendment dated February 28, 2003, amended independent claim 33. The Appendix Detailing Amendments to the Claims presents amended claim 33 as (underlining in original):

> 33. (Amended) A method for preparing an oral compacted composition in the form of a tablet, wherein the composition comprises entacapone, nitecapone or a pharmaceutically acceptable salt of entacapone or nitecapone, <u>and croscarmellose sodium in an amount of at least 6% by weight of the composition,</u> which comprises:

a) mixing a pharmaceutically effective amount of entacapone, nitecapone, or pharmaceutically acceptable salt of entacapone or nitecapone, one or more auxiliary agents and the croscarmellose sodium to obtain a first mixture;

b) compacting and crushing the first mixture one or more times to obtain a plurality of granules;

c) adding a lubricant, a glidant, or a mixture thereof to the granules to obtain a second mixture; and

d) compressing the second mixture into a tablet.

78. Applicants' Amendment dated February 28, 2003, stated:

Applicants have modified claim 21 to recite the presence of croscarmellose sodium in an amount of at least 6% by weight of the claimed composition. A similar amendment has been made to claim 33, which covers a method of making a composition. All independent claims 1, 32 and 33 now incorporate a composition having the recited amount of croscarmellose sodium.

79. Applicants' Amendment dated February 28, 2003, stated:

The claims have been amended to incorporate compositions comprising croscarmellose sodium in an amount of at least 6% by weight of the composition. That subject matter originally appeared in several dependent claims, such as claims 24 and 34 that were also rejected. As discussed during the personal interview, one skilled in the art would not have been motivated to make those inventions.

80. Applicants' Amendment dated February 28, 2003, stated (underlining and quoting in original):

If croscarmellose was believed to be completely effective at low levels, then one skilled in the art logically would not have been interested in using it in an amount of 6% or more. The Examiner mentioned at page 5 of the Final Office Action that it would have been obvious to "optimize" the amount of croscarmellose in a tablet to obtain a desired rate of dissolution of disintegration. Use of at least 6% surely would not have been regarded as a way to "optimize" the composition, but instead could have been regarded as rather pointless, if lower amounts were believed to be completely effective.

81. Applicants' Amendment dated February 28, 2003, stated:

The applicants surprisingly discovered that the best dissolution results for the oral compacted compositions of the invention are achieved when the amount of croscarmellose sodium is more than what is suggested in the art. Specification at page 6, last paragraph.

82. Applicants' Amendment dated February 28, 2003, stated (footnote omitted, quoting in original):

> The results plotted in Figure 2 starkly contradict the assumption that croscarmellose sodium would be "completely effective" at lower levels than those claimed. The significant differences between dissolution profiles obtained using 6%, 9%, 12% and 15% croscarmellose sodium shown in Figure 2 would not have been expected by someone under the impression that lower amounts are completely effective.

83. A Notice of Allowability was sent (attached hereto as Exhibit 14), and included a statement of Allowable Subject Matter that stated:

> The following is an examiner's statement of reasons for allowance:
> Instant claims are directed to a tablet composition comprising entacapone or nitecapone as an active substance and croscarmellose sodium in an amount of at least 6% by weight of the composition. Prior art of record teaches several superdisintegrants such as croscarmellose in the range of 2% to 4% for a complete effect. Applicants unexpectedly found that for entacapone and nitecapone, at least 6% or higher of croscarmellose is required in order to produce effective dissolution of the active substance. The claimed amounts of croscarmellose for the specific active substance would not have been readily obvious for one of an ordinary skill in the art because from the prior art teachings one of an ordinary skill in the art would have used superdisintegrants such as croscarmellose only in the range of 2% to 4%.

84. Applicants filed a Comments on Statement of Reasons for Allowance (attached hereto as Exhibit 15) that stated (quoting in original):

> Applicants actually have not represented that 6% or higher of croscarmellose sodium is required to produce "effective" dissolution. Applicants have instead argued that, if croscarmellose sodium was believed to be completely effective at lower levels when used in tablets, then one skilled in the art logically would not have been motivated to use it in the amount of 6% of more in the tablets of the invention. Aside from this point, applicants have provided several other reasons why the claimed invention, taken as a whole, would not have been obvious.

85. Applicants' Comment on Statement of Reasons for Allowance stated:

> Consistent with the Remington document of record, the reasons for allowance noted that one skilled in the art would have only used croscarmellose sodium in an amount of 2% to 4% in tablet compositions. The Information Disclosure Statement filed on September 30, 1998, enclosed a document cited as *A. Wade et al.* from the Handbook of Pharmaceutical Excipients. That document, considered by the Examiner as evidenced by an initialed 1449 form, mentions the possible use of croscarmellose sodium in tablets in amounts of

> 0.5-5% and in capsules in amounts of 10-25%. The allowed claims of this application recite tablet compositions. The Wade document mentions that amounts of 2% and 3% are normally used in tablets made by direct compression and wet granulation, respectively. The undersigned discussed this disclosure with the Examiner in the same telephone conversation referred to above. The Examiner noted that the Wade disclosure was not inconsistent with the reasons for allowance, especially when read in combination with the Remington disclosure.

86. Applicants have disclaimed amounts of croscarmellose sodium that are less than 6% by weight.

87. Prosecution history estoppel prevents the claims of the '530 patent from covering compositions comprising less than 6% by weight croscarmellose sodium under the doctrine of equivalents.

88. Prosecution history estoppel prevents the claims of the '530 patent from covering methods of manufacturing compositions comprising less than 6% by weight croscarmellose sodium under the doctrine of equivalents.

89. 4.85% croscarmellose sodium by weight is not an equivalent of 6% croscarmellose sodium by weight in the claims of the '530 patent.

90. 5% croscarmellose sodium by weight is not an equivalent of 6% croscarmellose sodium by weight in the claims of the '530 patent.

91. Orion is estopped from asserting that 4.85% croscarmellose sodium by weight and 5% croscarmellose sodium by weight are equivalents of 6% croscarmellose sodium by weight.

92. The manufacture, use, sale, offer for sale, or importation into the United States of Sun Global's entacapone composition does not, and will not, infringe any claim of the '530 patent under the doctrine of equivalents.

THIRD COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '194 PATENT

93. Sun Global is entitled to declaratory judgment that the '194 patent is invalid under the doctrine of obviousness-type double patenting over the '590 patent.

94. Sun Global is entitled to declaratory judgment that the '194 patent is invalid under the doctrine of obviousness-type double patenting over the '950 patent.

95. Sun Global is entitled to declaratory judgment that the '194 patent is invalid under 35 U.S.C. § 101 et seq., including 35 U.S.C. §§ 101, 102, 103, 112, 121, 156 and/or 253.

FOURTH COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '530 PATENT

96. No claim of the '530 patent found to be infringed would be valid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTH COUNTERCLAIM
DELETION OR CORRECTION OF ORANGE BOOK LISTING

97. Because the '194 patent is invalid, the claims of the '194 patent do not cover Comtan® or an approved method of using Comtan®.

98. Sun Global is entitled to declaratory judgment that the listing of the '194 patent in the Orange Book for Stalevo® should be deleted under 21 U.S.C. § 355 (j)(5)(C)(ii).

SIXTH COUNTERCLAIM
DELISTING OF THE '530 PATENT

99. The product insert for Comtan® does not indicate the amount of croscarmellose sodium in Comtan®.

100. On information and belief, Comtan® does not contain at least 6% croscarmellose sodium by weight of the composition.

101. The '530 patent claims an oral compacted composition in the form of a tablet, which comprises a pharmaceutically effective amount of entacapone, nitecapone, or pharmaceutically acceptable salt of entacapone or nitecapone, and croscarmellose sodium in an amount of at least 6% by weight of the composition.

102. Based on information and belief, the '530 patent does not cover Comtan®.

103. The listing of the '530 patent in the Orange Book should be deleted under 21 U.S.C. § 355 (j)(5)(C)(ii).

PRAYER FOR RELIEF

WHEREFORE, Counterclaimant Sun Global seeks a declaratory judgment against Orion as follows:

1. Dismissing the Complaint for Patent Infringement of the '194 patent against Sun Global in its entirety, with prejudice, holding that Orion shall take nothing by the Complaint, and that judgment be entered in favor of Sun Global;

2. Declaring that Sun Global has not, does not, and will not infringe the '194 patent or the '530 patent;

3. Declaring that Sun Global has not, does not, and will not induce and/or engage in contributory infringement of the '194 patent or the '530 patent;

4. Declaring that that '194 patent and the '530 patents are invalid;

5. Ordering that Orion delete the listing of the '530 patent in the Orange Book;

6. Ordering that Orion delete or correct the listing of the '194 patent in the Orange Book;

7. Declaring this case exceptional under 35 U.S.C. § 285;

8. Awarding Sun Global its Costs and Attorneys fees; and

9. Awarding Sun Global such other and further relief as the Court may deem just and proper.

Date: February 9, 2009

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